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Heart valve replacement with the Björk-Shiley and St Jude Medical prostheses: A randomized comparison in 178 patients

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In 178 patients, a randomized prospective comparison between the 60° spherical disc Björk-Shiley (BS) and the St Jude Medical (SJM) heart valve prostheses was performed. Four-week perioperative mortality was zero in the BS (n=84) and 4·3% in the SJM group (n=94). During a mean (±SD) follow-up of 52±20 months or 778 patient-years, late cardiac mortality per year was 2·4% in the BS and 2·2% in the SJM group. The yearly thromboembolic rates were 1·4% in the BS and 2·0% in the SJM group. There was no mechanical valve failure or haemolytic anaemia. Paravalvular leaks and major bleeding complications occurred at low rates in both groups (1·1% and 2·2% per year in BS; 0·7% and 1·7% per year in SJM). Functional results were similarly good with 96% of patients with BS valves and 95% of patients with SJM prostheses being in NYHA classes I and II, respectively.

We conclude that heart valve replacement with mechanical prostheses can be performed with equally good results using either the Björk-Shiley spherical disc valve or the St Jude Medical bileaflet prosthesis.

Introduction

Manufacturers of mechanical heart valve prostheses claim advantages such as improved haemodynamic performance, low thrombogenicity and a lower mechanical failure rate because of specific design characteristics[1,2,11,12]. Whether this is of clinical importance is largely unknown. Therefore a series of 178 patients were followed closely after valve replacement for an average 52±20 months — a total of 778 patient-years; in this series, either the Björk-Shiley (BS) 60° spherical disc valve or the St Jude Medical (SJM) bileaflet valve were selected for implantation in a randomized fashion.

Methods

PATIENTS

From January 1981 until October 1983, a randomized allocation of BS or SJM prostheses was made in 178 patients. These included 112 men and 66 women aged 1–76 years. In 84 patients 95 BS prostheses were implanted, and 94 patients received 109 SJM prostheses. Detailed patient characteristics are given in Table 1. The two patient groups were comparable as to age and sex distribution, location and number of implants as well as cardiac diagnosis. All candidates for a mechanical valve substitute were randomized and all accepted the valve suggested. In order to give comparable groups, randomization was performed according to underlying heart disease, pre-operative cardiac rhythm and concomitant surgery.

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OPERATIVE TECHNIQUES

All patients were operated on by the same surgical team who had previous extensive experience with both types of prostheses. All were operated on by sternotomy, using cardio-pulmonary bypass and cold potassium cardioplegia or coronary perfusion for myocardial protection. The prostheses were implanted with the interrupted suture technique.

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Table 1 Characteristics of 178 patients receiving a BS or SJM prosthesis in a randomized fashion

	BS	SJM	*P* value
N total	84	94	—
mean age ± SD, years	58·1 ± 11·5	55·4 ± 14·0	> 0·1
age range, years	19–76	1–76	—
male sex (%)	59·5	66·0	> 0·2
aortic valve replacement (%)	57 1	50 0	> 0 2
mitral valve replacement (%)	29·8	34·0	> 0·2
double valve replacement (%)	13·1	16·0	> 0·2
predominant aortic stenosis (%)	36·9	30·9	> 0·2
predominant aortic regurgitation (%)	20·2	19·1	> 0·2
predominant mitral stenosis (%)	16·7	13·8	> 0·2
predominant mitral regurgitation (%)	13·1	10·2	> 0·2
balanced lesions (%)	13·1	26	> 0·2
rheumatic heart disease (%)	84·5	77·7	> 0·2
myxoïd degeneration (%)	9·5	12·8	> 0·2
infectious endocarditis (%)	2·4	3·2	> 0·2
various etiologies (%)	3·6	6·3	> 0·2
concomitant coronary artery disease (a) (%)	15·5	11·7	> 0·2
papillary muscle dysfunction	2·4	2·1	> 0·2
preoperative NYHA grades III + IV	59·5	38·3	< 0·005
patients with ejection fraction < 50 (b) (%)	13·1	7·4	> 0·2
perioperative atrial fibrillation (%)	22·6	24·5	> 0·2
mean aortic size (mm)	24·3	23·5	
mean mitral size (mm)	27·9	27·6	
mean observation time (months)	52·3 ± 19·17	51·7 ± 18·9	—
range	(25–83 9)	(25–82·5)	—

(a) defined as a ⩾ 75% luminal narrowing of one or more major coronary vessels. (b) measured in all patients.

FOLLOW-UP

The patients were followed up at a specialized outpatient clinic, where at each visit a complete history, physical examination, chest X-ray, 12-lead resting ECG and laboratory parameters for haemolysis were taken. Echocardiography and Doppler sonography were not routinely used in these patients. A thromboembolic event was defined as any new transient or permanent neurological deficit or other peripheral arterial embolic episode[14]. The patients were seen 3 months postoperatively and yearly thereafter during a mean (± SD) of 52 ± 20 months (BS) and 52 ± 19 months (SJM). The follow-up duration ranged from 25 to 84 months. The number of patient-years in aortic valve replacement was 209 (BS) and 203 (SJM); in mitral valve replacement, 109 (BS) and 138 (SJM). All patients were on oral anticoagulants with coumarin derivatives, with INR values aimed at 2·8–4·3. A total of five patients were lost to follow-up (four in the Björk-Shiley group and one in the St Jude Medical group).

STATISTICAL ANALYSIS

Randomization was performed within subgroups of patients according to concomitant surgery, underlying disease, valve position and heart rhythm. For comparison between the groups, the chi-square test was used. Actuarial survival was calculated according to Kaplan and Meier[10].

Results

OPERATIVE AND EARLY MORTALITY

In the BS group, there was no death during operation or within the first 4 postoperative weeks. In the SJM group there were four deaths during the perioperative period (4·3%). One patient died during operation of an intractable aortic tear. During the 4-week postoperative course one patient

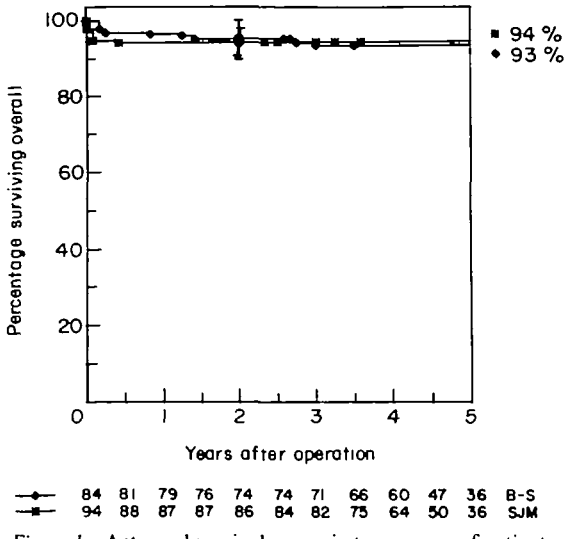

Figure 1 Actuarial survival curves in two groups of patients randomly receiving Björk-Shiley (BS) or St Jude Medical (SJM) heart valve prostheses. The small numbers below the time axis indicate patients at risk. The sections indicated in the curves show 95% confidence limits. The curves are age- and sex-adjusted for an expected survivorship in Switzerland (1982).

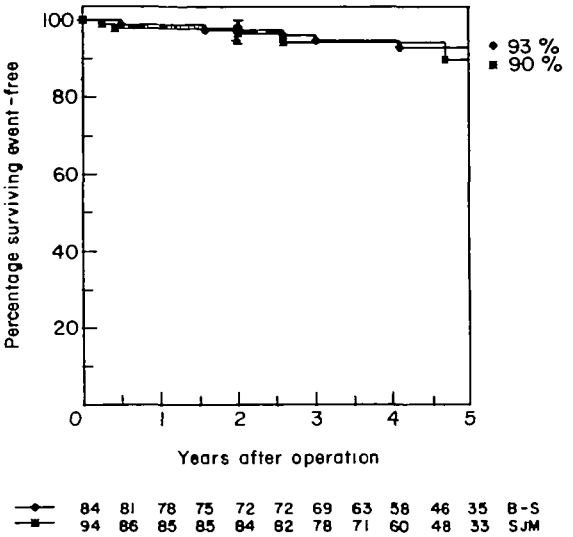

Figure 2 Actuarial incidence rates of thromboembolic complications in two groups of patients randomly receiving Björk-Shiley (BS) and St Jude Medical (SJM) prostheses. The small numbers below the time axis indicate patients at risk. The sections indicated in the curves show 95% confidence limits.

died from intractable sepsis, one patient from pump failure and one patient from renal failure.

LATE MORTALITY

Survival curves were virtually identical ($P > 0{\cdot}2$) in patients receiving BS and SJM prostheses (Fig. 1). During follow-up there were nine cardiac deaths in the BS group, resulting in a yearly cardiac mortality of 2·4%. There were five witnessed sudden deaths, two cases of pump failure and two patients with fatal haemorrhage. In addition there were three non-cardiac deaths (one suicide, carcinoma, pulmonary embolism in metastatic cancer). In the SJM group there were nine cardiac deaths, resulting in a yearly cardiac mortality of 2·2%. There were three witnessed sudden cardiac deaths, two patients with pump failure, one patient with endocarditis, two patients with fatal haemorrhages and one further patient with aortic rupture.

MECHANICAL VALVE FAILURE AND HAEMOLYSIS

There were no cases of mechanical valve dysfunction or thrombotic obstruction in either the BS or the SJM group. Anaemia with a haemoglobin value below 12 g% and a reticulocyte count of > 10‰ was observed in none of the patients. An LDH level exceeding 500 U l^{-1} was seen in one patient with a BS-valve with a paravalvular leak. In the two patients with SJM valves and paravalvular leaks, the LDH levels were normal.

THROMBOEMBOLISM

Thromboembolic event rates were 1·4% per year and 2·0% per year in the BS and SJM group, respectively. The actuarial incidence of thromboembolic complications was identical ($P > 0{\cdot}2$) in the two groups (Fig. 2) Thromboembolic events separated for valve position and type of prosthesis are shown in Figs 3 and 4. The differences between the two valve substitutes were not statistically significant, although the relatively high incidence of thromboembolic complications in BS mitral prostheses and SJM aortic valves is worth mentioning, contrasting with the lack of thromboemboli in patients after BS aortic valve replacement. The detailed thromboembolic rates according to prosthesis type and location are shown in Table 2. Thromboembolism occurred with adequate anticoagulation (i.e. INR levels between 2·8–4·3) in four of five cases in the BS group, and in three of eight cases in the SJM group. There were no permanent sequelae in two of five BS and seven of eight SJM patients. There were no fatal thromboembolic events.

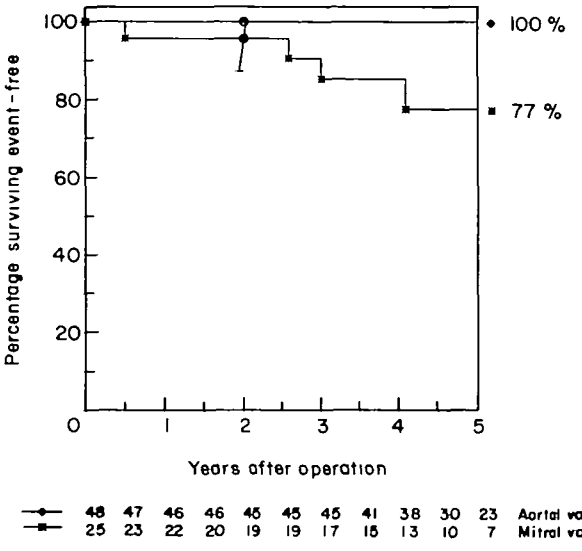

Figure 3 Actuarial incidence rates of thromboembolic complications in BS prostheses, separated into aortic and mitral valves. The small numbers below the time axis indicate patients at risk. The sections indicated in the curves show 95% confidence limits.

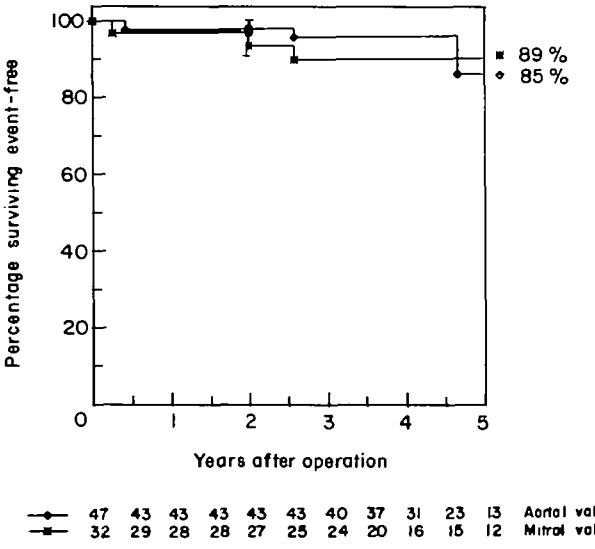

Figure 4 Actuarial incidence rates of thromboembolic complications in SJM protheses separated into aortic and mitral valves. The small numbers below the time axis indicate patients at risk. The sections indicated in the curves show 95% confidence limits.

PARAVALVULAR LEAKS

Angiographically documented paravalvular leaks necessitating reoperation occurred in one patient with a BS aortic valve and in two patients with SJM mitral valves. In addition, there were paravalvular leaks without haemodynamic significance in three patients with BS (two aortic and one mitral) prostheses and one patient with an SJM aortic valve, all documented by Doppler echocardiography. This gives a paravalvular leak

Table 2 Thromboembolic rate per 100 patient years of 95 patients after aortic valve replacement (48 BS, 47 SJM), 57 patients after mitral valve replacement (25 BS, 32 SJM) and 26 patients after double valve replacement (11 BS, 15 SJM)

	BS	SJM	
Aortic position	0	3·0	n.s.
Mitral position	4·6	2·2	n.s.
Double implant	1·9	0	n.s.
All	1·4	2·0	n.s.

n.s. = not significant.

incidence of 1·1% and 0·7% for BS valves and SJM prostheses, respectively.

COMPLICATIONS SECONDARY TO ANTICOAGULATION

Lethal bleeding occurred in two patients with a BS valve (both cerebral haemorrhages) and in two patients with a SJM valve (one cerebral, one gastrointestinal). In none of these patients was the prothrombin time known at the time of death. Major non-fatal bleeding occurred in six patients with BS valves (four gastrointestinal, one intracranial, one pericardial) and in five patients with SJM valves (two gastrointestinal, two intracranial, one ovarian). Minor bleeding occurred in one patient in each group (one epistaxis, one subcutaneous). The annual incidence of major bleeding complications was therefore 2·2% and 1·7% for BS and SJM valves, respectively.

Cumulative yearly event-free rates defined as free from death, thromboembolism, reoperation, valve dysfunction, endocarditis and major bleeding are shown in Fig. 5. No significant difference ($P > 0·2$) is seen between the two groups with BS and SJM prostheses. The detailed event-free rates according to prosthesis type and location did not show any significant difference and are given in Figs 6 and 7.

FUNCTIONAL RESULTS

Of the patients with BS prostheses 68% were in class I and 28% in class II of the NYHA postoperatively. Corresponding figures for the SJM group were 65% in class I and 30% in class II (Fig. 8). Therefore, postoperatively 96% and 95% of patients in the BS and SJM groups were in NYHA classes I or II, respectively. The percentage of patients in sinus rhythm pre- and postoperatively was 73 and 79 in BS vs 75 and 88 in SJM patients.

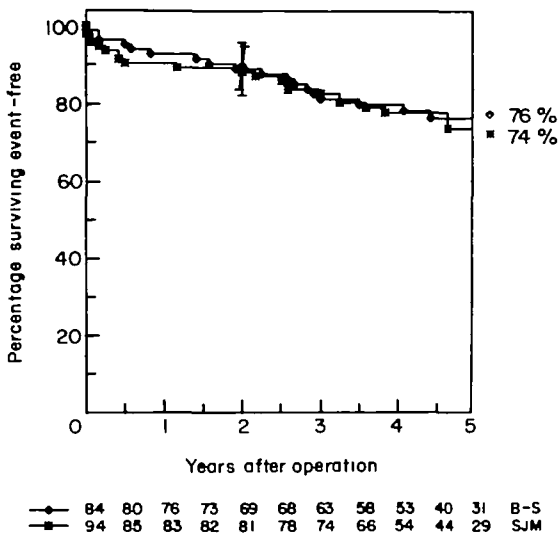

Figure 5 Cumulative yearly event-free rates (event = death, reoperation, thromboembolism, major bleeding, valve dysfunction, infectious endocarditis). The small numbers below the time axis indicate patients at risk. The sections indicated in the curves show the 95% confidence limits.

Normalization of a preoperatively abnormal cardiothoracic ratio occurred in 37% of BS and 41% of SJM patients (Table 3).

Discussion

Two prostheses of quite different design were compared in a randomized prospective study in patients eligible to receive a mechanical valve substitute. Despite differences in valve area and haemodynamic flow patterns[11], clinical results with the two prostheses were nearly identical in our population.

Operative and early (4 weeks) mortality in our total population was 2·2%, which is lower than figures from other centres[5,7,13]. This is probably due to the fact that only few patients with ischaemic heart disease, with ejection fraction below 50% and in NYHA class IV were included. All these factors are known to influence perioperative mortality and postoperative prognosis[5]. There was no significant difference in mortality between the two groups of patients. Similarly, late annual mortality in both groups was low, being 2·4% for patients with BS, and 2·2% for patients with SJM prostheses. This compares favourably with data reported from Duncan *et al.*[7], who found a yearly mortality rate of 2·5% in 253 patients after aortic or mitral valve

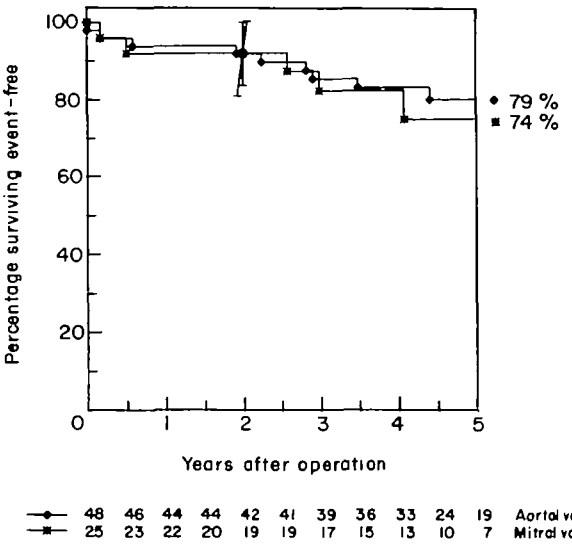

Figure 6 Cumulative yearly event-free rates (event = death, reoperation, thromboembolism, major bleeding, valve dysfunction, infectious endocarditis) for BS prostheses, separated into aortic and mitral valves. The small numbers below the time axis indicate patients at risk. The sections indicated in the curves show the 95% confidence limits.

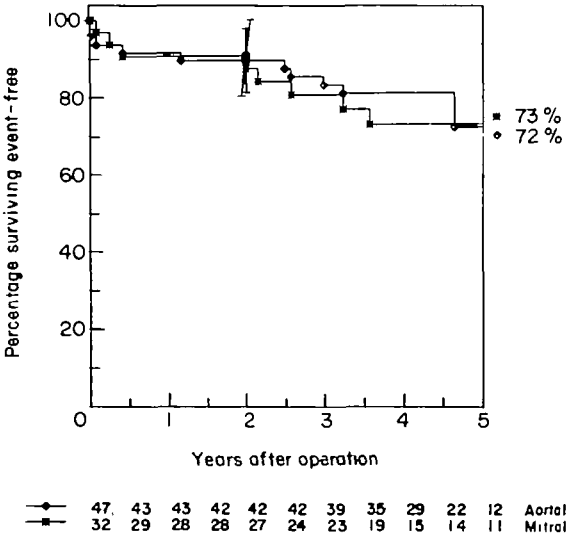

Figure 7 Cumulative yearly event-free rates (event = death, reoperation, thromboembolism, major bleeding, valve dysfunction, infectious endocarditis) for SJM prostheses, separated into aortic and mitral valves. The small numbers below the time axis indicate patients at risk. The sections indicated in the curves show 95% confidence limits.

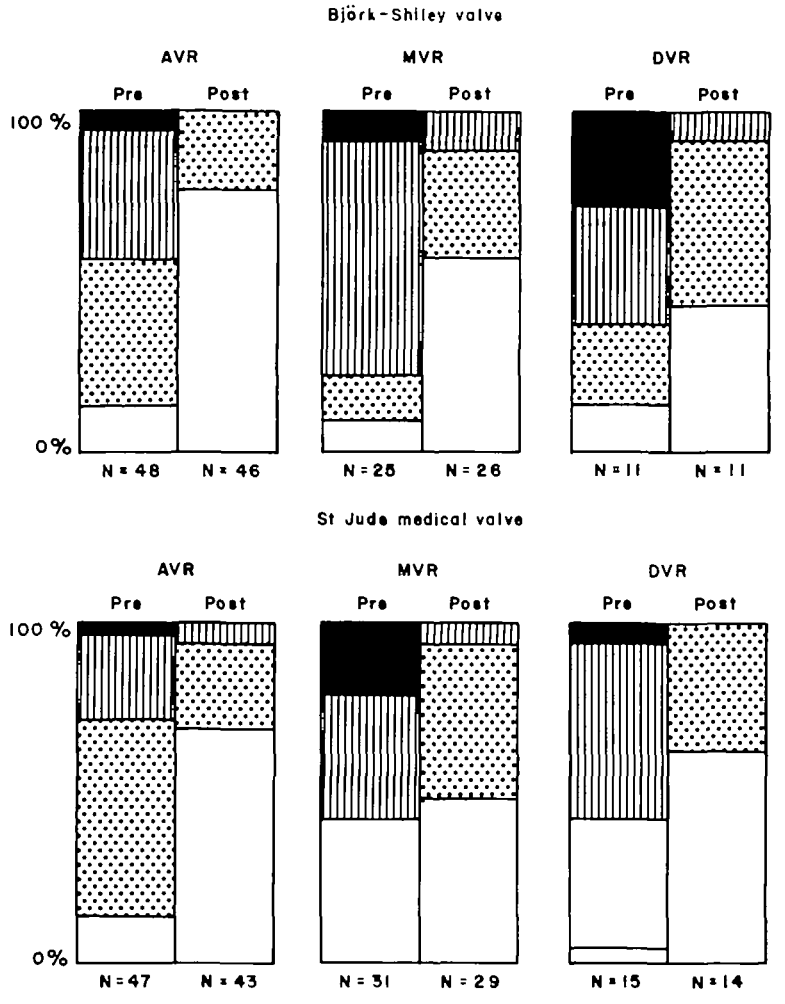

Figure 8 Functional classification according to the New York Heart Association (NYHA) before and after operation in two groups of patients with Björk-Shiley (BS) and St Jude Medical (SJM) heart valve prostheses. AVR = aortic valve replacement; MVR = mitral valve replacement; DVR = double valve replacement. □ = class I; ⊡ = class II: ▥ = class III; ■ = class IV.

Table 3 Pre- and postoperative rhythm- and chest X-ray findings in patients with BS and SJM prostheses

	BS	SJM
% patients in sinus rhythm pre- and post-operatively	73/79	75/88
% patients with a CTR < 0·5 pre- and post-operatively	17/54	30/71

replacement with the SJM prosthesis and with findings from Sethia and coworkers[13], who reported a yearly mortality of 2·9% in 729 patients with the standard BS valve.

Thromboembolic events occurred with an equally low incidence in the BS (1·4% per year) and SJM group (2·0% per year). These findings are in contrast with those reported by Horstkotte *et al.*[8], who found a thromboembolic rate of 12·5% in the first year after mitral valve replacement with the BS prosthesis, but no thromboemboli with the SJM

mitral valve. However, in their study group allocation was not performed in a randomized fashion, so the BS group included more patients with mitral regurgitation, accompanying valve disease, long history of symptoms, prior valve surgery and atrial fibrillation. In a later publication, the same authors reported a lower thromboembolic rate of 2·82 and 1·93 per 100 patient-years after BS mitral or aortic valve replacement, respectively, which was still higher than their figures found after valve replacement with the SJM prosthesis (0·93% mitral, 0·73% aortic)[9]. Other authors found, as we did, a similar incidence of thromboembolism in different mechanical valves. In a prospective study, Chesebro *et al.*[4] found an incidence of thromboembolism, ranging from 1·2 to 1·8% per year in patients after valve replacement with the Starr-Edwards (SE), BS or SJM prostheses. Chaux *et al.*[3] described comparable rates of thromboembolism with the BS and the SE prostheses. In another prospective study, Douglas *et al.*[6] observed a thromboembolic rate of 2·8% per patient-year after aortic valve replacement with the SJM prosthesis, which was not significantly higher than the 1·5% recorded after implantation of an aortic porcine heterograft.

When our data were treated with the actuarial method, 93% of patients with BS and 90% of patients with SJM prostheses were free of thromboembolic events after 5 years. These figures are comparable to those of Sethia *et al.*[13], who observed a freedom from thromboembolic events in 94% of their patients with BS prostheses after 4 years. Seven of the 13 thromboembolic events in our study occurred with adequate anticoagulation (four of five in the BS group and three of eight in the SJM group). Analysis of thromboembolic events according to valve location showed no significant differences between valve types.

A paravalvular leak occurred in seven of our patients (four BS and three SJM), necessitating reoperation in three patients (one BS, two SJM). This corresponds to an annual reoperation rate of 0·4% in the BS group and 0·8% in the SJM group. These figures again compare well to those reported by Sethia *et al.*[13], who found a reoperation rate of 0·8% per year in his patients receiving BS prostheses.

The functional results were equally good in both groups. In the BS group, 60% of patients were preoperatively in NYHA classes III or IV, but only 4% were in NYHA class III after valve replacement. In the SJM group, 39% of all patients were preoperatively in NYHA classes III and IV and only 5% were in NYHA class III after surgery. Similar functional results were reported by Duncan[7] and Horstkotte[8]. This equally good functional result was achieved in both groups despite the fact that patients receiving a BS prosthesis were preoperatively more symptomatic.

Thus, cumulative complication rates were similarly low and equally excellent functional results were achieved despite a difference of the preoperative functional state of patients in the two groups. As regards all other relevant variables, the two groups were comparable. This was achieved by using several randomization subgroups according to underlying disease, preoperative heart rhythm and concomitant surgery. This is also the reason for the different number of patients in the two groups.

The rather small number of patients in the different subgroups in this study makes a statistical analysis of our data difficult. However, due to the low event rate expected one would have to include over 3000 patients in each group to detect a statistically significant difference between two groups with a power of 0·8 and a P value of 0·05. Therefore it did not seem reasonable to plan a much larger study, because even a multicentre approach would not have significantly altered the weak statistical power[15].

From the results of this randomized prospective study, there seems to be no clinical relevance for the manufacturers' claim of a lesser degree of transvalvular regurgitation in the BS nor a lower thrombogenicity in SJM prostheses.

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